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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/623,928 | 07/21/2003 | Ulrich Posanski | 4-20017F | 6463 |

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

| EXAMINER | |
|---|---|
| FUBARA, BLESSING M | |
| ART UNIT | PAPER NUMBER |
| 1618 | |
| MAIL DATE | DELIVERY MODE |
| 11/26/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/623,928 | POSANSKI, ULRICH | |
| | Examiner | Art Unit | |
| | BLESSING M. FUBARA | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 8/11/08. Claims 11 and 17 are amended. Claims 11-20 are pending.

**Previous rejections that are not reiterated herein are withdrawn.**

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11-14 and 16-19 remain rejected under 35 U.S.C. 102(b) as anticipated by Polanski (GB 2 228 198 A) for reasons of record and reiterated herein below.

Polanski discloses pharmaceutical composition that contains cyclosporine meeting the limitations of the active agent in claims 11, 13 and 17; carrier composition that contains oils, tenside having HLB of 10 and cremophor (Examples 1 and 2; pages 11-13, page 16), meeting the carrier limitation often the claims. On page 10, line 4, Polanski describes the composition as not being aqueous meeting the requirement to exclude hydrophilic phase. The amounts in the examples meet the amounts in the claims.

### *Response to Arguments*

3. Applicant's arguments filed 8/11/08 have been fully considered but they are not persuasive.

4. Applicant argues that Polansky does not teach sorbitan fatty acid esters of claim 15 namely: sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate. sorbitan tristearate, sorbitan monooleate, sorbitan trioleate and sorbitan sesquioleate, applicant then arrives at saying that Polansky does not teach claims 11-19. The examiner disagrees. Claim 11 does not recite the specific sorbitan fatty esters of claim 15. Polansky teaches sorbitol complete or partial ester (see page 11, at item A; page 28, 4th full paragraph), which in general and broad sense meet claims 11 and 14. Therefore, because Polansky teaches sorbitol ester, complete or partial, noting that sorbitan oleate or palmitate are esters derived from sorbitol and fatty acids; with sorbitan oleate having HLB of 4.3 (evidenced as CAS # 1338-43-8), which is less than 10 HLB. Furthermore, page 13, lines 1-3 under section d.2, talks about the sorbitan fatty acids being available under the trade name TWEEN and TWEEN 61 has an HLB of 9.6, which is less than 10 as evidenced by Rabiskova (abstract) and also by column 3, lines 65-67 of US RE33759, which identifies TWEEN 61 and 81 having HLB values in the range of 9.6 to 11.4.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polanski (GB 2 228 198 A).

7. Polanski is described above. The formulation of Polanski is an oral formulation (title, abstract). Polanski does not specifically teach tablets or capsules as recited in claim 20. However, tablet and capsule are oral dosage forms. Therefore, taking the broad oral teaching of Polanski, the person one having ordinary skill in the art would have reasonable expectation of success in formulating the dosage form of Polanski in tablet or oral dosage form for oral administration.

***Response to Arguments***

8. Applicant's arguments filed 8/1/08 have been fully considered but they are not persuasive.

9. Applicant argues that Polanski does not suggest making the formulation of claim 11, so that one skilled in the art at the time the invention was made would not have found it obvious to practice the process of claims 19 and 20. The examiner disagrees. The response to applicant's argument under 35 USC 102 shows that Polanski indeed uses sorbitol esters and TWEEN; Polanski also teaches that the form of the composition can be granules or tablets or capsules for oral administration (see page 27, 3rd full paragraph).

10. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavanak (US 5,639,724).

Cavanak discloses composition containing cyclosporin as the active agent, glycerol fatty acid ester and tenside having HLB of 10 (abstract) meeting the requirements of claims 11-18. Cavanak describes a variety of cyclosporin compositions that contains sesame oil, TWEEN or CREMOPHOR , triglyceride, neutral oils (column 5, lines 12-20), tri- and di-glycerides,

CREMOPHOR (column 8, lines 12-18), sorbitan monolaurate (column 14, lines 43-67) and the process of combining the components into the formulation meets process claim 20. See also column 13, lines 45-67; column 14, lines 6-43. Cavanak does not describe the presence of hydrophilic phase. Cavanak contemplates oral dosages of granules, tablets, capsules and drink solutions (Column 21, lines 15 and 16) meeting claim 20

Cavanak does not however teach the percent amounts of the carrier components. However, Cavanak teaches the general conditions of the composition and differs by not teaching the respective amounts. But in general, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, taking the teachings of Cavanak, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success to formulate the dosage form of Cavanak using amounts of the components that when combined would be effective in achieving the desired dosage form.

***Response to Arguments***

11. Applicant's arguments filed 8/11/08 have been fully considered but they are not persuasive.

12. Applicant argues that Cavanak prefers TWEEN 40 and TWEEN 80, all of which have HLB of greater that 10. The examiner agrees with the applicant that Cavanak does not teach sorbitan monolaurate in column 14, lines 43-47 and that the polyoxyethylene sorbitan fatty esters

are commercially available as TWEEN. But, it is well established that consideration of reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art to a person of ordinary skill in the art. In the present case, Cavanak contemplates using sorbitol esters, partial or complete (column 13, line 51) and sorbitan palmitate and oleate are known examples of sorbitol esters and have HLB less than 8, see CAS # 1338-43-8 as evidence. Furthermore, column 14, line 46 talks about the sorbitan fatty acids being available under the trade name TWEEN and TWEEN 61 has an HLB of 9.6, which is less than 10 as evidenced by Rabiskova (abstract) and also by column 3, lines 65-67 of US RE33759, which identifies TWEEN 61 and 81 having HLB values in the range of 9.6 to 11.4. Therefore, one having ordinary skill in the art at the time the invention was made has reasonable expectation of success that using the suggested ester of sorbitol or TWEEN having desired HLB would lead to the expected formulation taught by Cavanak.

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 11-20 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable, for reasons of record and reiterated herein below, over claims 1, 27-35 and 37, 1-10, 1-10 of copending Application Nos. 11/453504, 10/961785 and 10/623887 respectively. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated, or would have been obvious, over the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In the present case, claims 11 and 13 of the examine application reads on at least claims 1 and 3 of co-pending applications 10/961,785 and 10/623,887 and claims 1, 27, 29, 31-33 and 37 of co-pending 11/453,504.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

15. Applicant's arguments filed 8/11/08 have been fully considered but they are not persuasive.

16. Applicant has indicated filing a terminal disclaimer when there is an indication of allowable subject matter and requests the rejection to be held in abeyance. But, the provisional

obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

No claim is allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618